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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,845	01/17/2006	Tatsuo Hoshino	21419 US C038435/0185660	2036

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	**PAPER NUMBER**
1652	
MAIL DATE	**DELIVERY MODE**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,845	HOSHINO ET AL.	
	Examiner	Art Unit	
	IQBAL H. CHOWDHURY	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-15* is/are pending in the application.

4a) Of the above claim(s) *3,8,12 and 13* is/are withdrawn from consideration.

5)☒ Claim(s) *15* is/are allowed.

6)☒ Claim(s) *1,4-7,9-11 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

Claims 1 and 3-15 are currently pending in the instant application.

In response to a previous Office action, a final action (mailed on 9/7/2007), Applicants filed a response and amendment received on 5/12/2008, amending claims 1 and 4 is acknowledged. Claims 2 remain cancelled, and Claims 3, 8, and 12-13 remain withdrawn as drawn to nonelected invention.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/12/2008 has been entered.

Claims 1, 4-7, 9-11 and 14-15 are under consideration and are present for examination.

Applicants' arguments filed on 5/12/2008 have been fully considered but are not deemed persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Maintained - Claim Rejections - 35 U.S.C. § 112

Previous rejection of Claims 1, 4, 7 and 11 under 35 U.S.C. 112, first paragraph, enablement requirement is maintained and claim 14 is included in this rejection. This rejection has been discussed at length in previous Office Action. The rejection is maintained for the following reasons.

Applicants argue that with a view towards furthering prosecution, claims 1 and 4 (from which claims 7 and 11 depend) have been amended to recite "(c) a DNA sequence encoding a polypeptide having vitamin B6 phosphate phosphatase activity, wherein said polypeptide is at least 95% identical to the amino acid sequence of SEQ ID NO:10" and "(d) a DNA sequence encoding a polypeptide having vitamin B6 phosphate phosphatase activity and is at least 95% identical to the DNA sequence of SEQ ID NO:9".

This is not found persuasive because claims are not limited to this in view of part a) and b) of claims 1 and 4 which are broader than parts (c) and (d). Part (a) of claim 1 is broader in the recitation “a DNA sequence”, which interprets any fragments of SEQ ID NO: 9 without any structural feature, and part (b) is broader in the recitation “hybridization ------ washing ---- 50oC”, the temperature, which allows many DNA fragments to remain bound with SEQ ID NO: 9; however, part (c) and (d) has a specific structural feature, i.e. DNA which is 95% identical to SEQ ID NO: 9 or encodes protein that is 95% identical to SEQ ID NO: 10.

Applicants also argue that as it is well accepted, even a "considerable amount" of experimentation is permissible if it is merely routine or if the specification provides reasonable amount of guidance. In view of the foregoing amendments, we note that the specification provides ample disclosure sufficient to inform a skilled artisan that the Applicants enabled the currently claimed vectors, plasmids, and recombinant microorganisms. Furthermore, the specification discloses two examples and four detailed Figures that provide sufficient instruction to one skilled in the art on how to make and use the currently claimed recombinant microorganism, vector, or plasmid encoding vitamin B phosphate phosphatase. Thus, identifying

a recombinant microorganism capable of encoding, vitamin B6 phosphate phosphatase according to the amended claims is a matter of applying the disclosure in the specification of how to make such microorganisms an testing the vitamin B6 production of the microorganisms compared to *Sinorhizobium meliloti* IFO 14782. *(See* Table 6 of the Specification). It is submitted that such activity is not undue experimentation.

Applicant's amendment to the claims and arguments have been fully considered but are not deemed persuasive to overcome the rejection on scope of enablement under 35 USC 112, 1st paragraph for the following reasons.

The specification while being enabling for a vector comprising an isolated DNA with SEQ ID NO: 9, which encodes a polypeptide vitamin B6 phosphate phosphatase enzyme of SEQ ID NO: 10 isolated from S. meliloti, does not reasonably provide enablement for a vector comprising any DNA fragment of SEQ ID NO: 9 due to the recitation of "**a** DNA sequence of SEQ ID NO: 9", which interprets any DNA fragment of SEQ ID NO: 9, or any DNA fragment that remain hybridized with SEQ ID NO: 9 due to the recitation "a fragment thereof" or any fragment of SEQ ID NO: 9 after washing at 50oC or any DNA fragment of SEQ ID NO: 9 due to the recitation of "comprising **a** polynucleotide sequence of SEQ ID NO: 9 (claim 14).

The specification does not contain any disclosure of the structures of all DNA fragments that will hybridize with the sequence of SEQ ID NO: 9 and encodes a protein having recited vitamin B6 phosphatase activity at the recited hybridizing and washing conditions. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNAs having any structures broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by the nucleic acid molecule, determines its

structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence (SEQ ID NO: 9) of only one protein of SEQ ID NO: 10.

The specification does not support the broad scope of the claims which encompass any DNA encoding a polypeptide having the ability to hybridize with the DNA of SEQ ID NO: 9 or any fragments thereof under recited stringent hybridization and washing conditions, and the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA encoding a polypeptide having the ability to dephosphorylate vitamin B6 phosphate (VB6P), which will hybridize with the DNA of SEQ ID NO: 9 under recited stringent hybridization and washing conditions The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any DNA molecule having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The Examiner acknowledges the amendment to the claims but washing steps of hybridization are still broad in the context of "50oC" because washing at 50oC is not enough highly stringent condition, which would allow any DNA fragment having sequence similarity to any part of SEQ ID NO: 9, which may not have any relation with encoding protein of SEQ ID NO: 9 and remain bound to the target sequence SEQ ID NO: 9, and one of skilled in the art cannot practice the claimed invention by hybridizing any DNA molecules and washing at 50oC by identifying any or all DNA sequence, which would require undue experimentation for finding a nucleic acid molecule having desired biological functions. Therefore, the rejection is maintained.

This rejection can be overcome by deleting "fragments thereof" (part (b) line 3) and washing at "50oC" (part (b), line 7) and replacing the phrase "comprising a polynucleotide sequence of SEQ ID NO: 9" with "comprising the polynucleotide sequence of SEQ ID NO: 9" (claim 14) and, replacing "a DNA sequence (part a) of claims 1 and 4 with "the DNA sequence".

New-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7, 11 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are directed to a vector comprising any DNA fragment of SEQ ID NO: 9 due to the recitation of "**a** DNA sequence of SEQ ID NO: 9", which interprets any DNA fragments of SEQ ID NO: 9 (part (a) of claims 1 or 4), or any DNA fragment of SEQ ID NO: 9 due to the recitation of "comprising **a** polynucleotide sequence of SEQ ID NO: 9 (claim 14).

The specification teaches the structure of only single representative species of such DNAs, i.e. SEQ ID NO: 9. Moreover, the specification fails to describe any other representative species by any identifying characteristics, properties other than functionality of the DNA encoding the polypeptide. Given this lack of description of representative species encompassed by the genus of DNAs of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention. This rejection can be overcome by replacing the phrase "comprising a polynucleotide sequence of SEQ ID NO: 9" with "comprising the polynucleotide sequence of SEQ ID NO: 9" (claim 14) and, replacing "a DNA sequence (part a) of claims 1 and 4 with "the DNA sequence".

New-Claim Rejections - 35 USC § 112, First Paragraph (new matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4, and dependent claims 5-7 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 4 are directed to a vector comprising "a DNA sequence encoding a polypeptide having vitamin B6 phosphate phosphatase activity, which is at least 95% identical to SEQ ID NO:10 (part (c)) or at least 95% identical to the DNA sequence of SEQ ID NO: 9 (part (d))".

There is no indication in the specification of the recitation "95%" as recited in the claims, within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

Withdrawn-Claim Rejections - 35 USC § 103

Previous rejection of Claims 2, 4, 7 and 11 under 35 U.S.C. 103(a) as being unpatentable over Capela et al. (GenBank Accession No. AL591783 for nucleic acid, created 8/1/2001 see IDS, and GenBank Accession No. Q92SG4, for protein, created 12/1/2001) and Jang et al. (Human pyridoxal phosphatase. Molecular cloning, functional expression, and tissue distribution, J Biol Chem. 2003 Dec 12; 278(50): 50040-6. Epub 2003 Sep 30) is withdrawn in view of applicants arguments regarding foreign priority documents of the instant application. The Examiner acknowledges the foreign priority document and granted the effective filing date of 9/27/2002, which results disqualification of Jang et al. reference that is not a prior art.

New-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 7 and 11, 14 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Capela et al. (GenBank Accession No. AL591783 for nucleic acid, created 8/1/2001 see IDS, and GenBank Accession No. Q92SG4, for protein, created 12/1/2001, see PTO 892) in view of common knowledge. Instant claims are drawn to a DNA encoding vitamin B6 phosphate phosphatase or pyridoxal phosphatase having at least 95% identity to SEQ ID NO: 9 encoding a protein having at least 95% identity to SEQ ID NO: 10 or any fragments thereof, a vector comprising said DNA sequence, a host cell of E. coli, a process for preparing cell extract from transformed host cell.

Capela et al. teach a DNA, and identify a putative oxidoreductase type protein encoded by the open reading frame (ORF), which is 99.5% identical to SEQ ID NO: 9 of the instant application, inherently a vitamin B6 phosphate phosphatase protein. Capela et al. do not teach a

vector comprising said sequence, transformed host cell and a method of producing said protein in transformed host cell and extraction of cell lysate.

However, inserting an ORF of the nucleic acid of Capela et al. into a vector to produce the protein encoded by the open reading frame in order to determine its function is within the knowledge of the one of ordinary skilled in the art and which is widely used in the prior art for producing a new protein for functional studies.

It would have been obvious to one to ordinary skill in the art at the time of the invention was made to combine the teachings of Capela et al. with the common knowledge to clone the DNA of Capela et al. in a vector, transform an E. coli host cell, a process for producing said protein in E. coli cells, preparing cell extract.

One of ordinary skill in the art would have been motivated for cloning the DNA of Capela et al. in a vector, transform an E. coli host cell, a process for producing the protein in said E. coli cell, extract the cell lysate, which is widely known in the art for producing a new protein for functional studies.

One of ordinary skill in the art would have a reasonable expectation of success because cloning a gene, expression and a process for producing said protein is widely known and used in the art for over-producing interested protein in bacterial system.

Conclusion

Claims 1 and 3-15 are pending.

Claims 3, 8, and 12-13 are withdrawn.

Claim 15 is allowed.

Claims 1, 4-7, 9-11 and 14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed, can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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